



Patent Term Adjustment

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Overview

- Introduction to Patent Term Adjustment
- Why Patent Term Adjustment Was Established
- Compact Prosecution
- Patent Term Adjustment Statutory Scheme
- Open Issues
- Tips for Maximizing Patent Term Adjustment



Patent Term Adjustment

- Patent Term Adjustment ("PTA") was established by the American Inventors Protection Act of 1999 and codified at 35 U.S.C. § 154(b)
- Current PTA should be distinguished from:
 - The old regime of PTA, which applied to patents issuing on applications filed on or after June 8, 1995, but before May 29, 2000; and
 - Patent Term Extension codified at 35 USC § 156 to compensate for delays associated with approval by the Food and Drug Administration ("FDA")
- This presentation will not discuss the old PTA regime or Patent Term Extension



Why PTA Was Established

- Prior to 1995, US patents were entitled to a patent term of 17 years from issue
- In 1995, the US changed to the patent term to 20 years from the earliest effective US non-provisional filing date to implement the TRIPS Agreement
- Under a 17-years-from-issue term, examination delays do not diminish the patent term
- Under a 20-years-from-earliest-effective-filing-date term, examination delays erode the effective patent term
 - If examination takes three years, the patent can be enforced for 17 years
 - If examination takes five years, the patent can only be enforced for 15 years



Why is PTA Important?

- PTA lengthens a patent's term
- PTA can be extremely valuable for products that have long development and/or regulatory approval lifecycles, such as:
 - Pharmaceuticals
 - Medical devices
 - University-licensed technologies
- A “blockbuster drug” is a drug that generates at least \$1 billion in annual revenue. Therefore, each additional day of patent term for a blockbuster drug equals at least \$2.7 million per day in revenue.



Compact Prosecution

- What is “Compact Prosecution”?^{*}
 - Conducting an initial search which is as complete as possible;
 - Citing pertinent art on the record in keeping with the scope of the claims as well as significant aspects of the disclosed invention;
 - Issuing a complete first Office Action which clearly explains the Examiner’s position on each essential issue; and
 - Identifying allowable subject matter in an effort to expedite prosecution.
- PTA law and rules generally reflect compact prosecution principles

^{*} USPTO, “Best Practices in Compact Prosecution: Awareness Workshop,”
http://www.uspto.gov/patents/law/exam/compact_prosecution.pdf



Patent Term Adjustment Statutory Scheme

- Three types of delays:
 - "A" Delays
 - "B" Delays
 - "C" Delays
- Limitations on PTA
 - Double-counting prohibited
 - Adjusted term may not extend beyond expiration date specified in any filed (and approved) terminal disclaimer
 - Reductions in PTA for applicant delays
- Procedures for determining and correcting PTA



“A” Delays

- 35 U.S.C. § 154(b)(1)(A) provides adjustment of patent term for administrative delays (“the 14-4-4-4 Rule”)
- Guarantee of prompt action requires USPTO to:
 - Issue an Office Action within 14 months after application filing or national phase entry under 35 U.S.C. 371(b) or 35 U.S.C. 371(f)
 - Respond to a reply or appeal within 4 months from the date that the reply or appeal was filed
 - Act on the application within 4 months after a decision from the Patent Trial and Appeal Board (PTAB) or from Federal Court
 - Issue the patent within 4 months after payment of the issue fee



When Does the National Stage Commence?

- There are two paths for commencing the national phase:
 - § 371(f) - Applicant commences the national phase upon express request and completion of the requirements of § 371(c) upon filing
 - § 371(b) – Applicant commences the national phase upon filing of application and expiration of the time limit under PCT Articles 22 or 39
- Commencement of the national phase at 30 months does not require the completion of the § 371(c) requirements (e.g., oath/declaration)



“B” Delays

- 35 U.S.C. § 154(b)(1)(B) provides guarantee of no more than 3-year application pendency (“the 3 Year Rule”):
 - The USPTO generally must issue a patent within 3 years from the filing date or from entry date into the U.S. national stage
 - Exceptions include applicant delays
- “B” Delay excludes time consumed by:
 - Requests for Continued Examination*
 - Appeals (both within the USPTO and in Federal Courts)

* Exclusion of time after certain RCE: *Novartis v. Lee*, 740 F.3d 593 (Fed. Cir. 2014)



How is “B” Delay Affected by RCE Filings?

- *Novartis v. Lee*, 740 F.3d 593 (Fed. Cir. 2014)
- USPTO rules state that the filing of an RCE terminates the accrual of "B" Delay for failure to issue a patent within three years
- Novartis challenged that:
 - while the USPTO can exclude time consumed by consideration of an RCE when determining whether it failed to issue a patent within three years (the “trigger”),
 - the USPTO cannot exclude the time consumed by the RCE when calculating the PTA resulting from the failure to issue a patent within three years (the “remedy”)
- Under this approach, an RCE first filed more than three years after filing would not limit "B" Delay
- Alternatively, the period between allowance and issuance should not be excluded from "B" Delay as “time consumed by continued examination”



How is “B” Delay Affected by RCE Filings?

- *Novartis* - Federal Circuit held that any time consumed by continued examination is subtracted in determining the extent to which the period of application pendency exceeds three years
 - Regardless of when RCE is filed
- Time consumed by RCE does not include the time after a notice of allowance, unless the USPTO actually resumes examination of the application after allowance
- 37 CFR 1.703 and 37 CFR 1.704
 - Adopts the two rules above (1.703 effective January 9, 2015 and 1.704 effective March 10, 2015)
 - Includes another change:
 - The submission of an RCE after a notice of allowance has been mailed will constitute a failure to engage in reasonable efforts to conclude examination; reduces PTA



“C” Delays

- 35 U.S.C. § 154(b)(1)(C) provides adjustment of patent term for:
 - Interferences
 - Secrecy orders
 - Successful appellate review

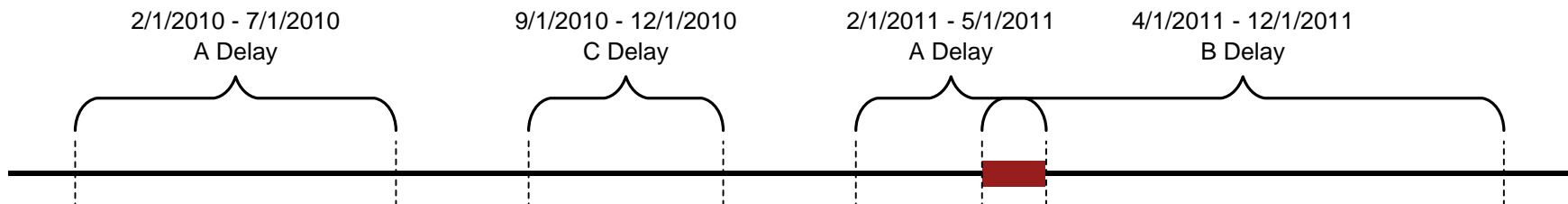


Overlapping Periods of PTA

- 35 U.S.C. § 154(b)(2)(A) states:

To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

- Under *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010) delays only overlap if they occur on the same day
- $PTA = \text{"A" Delay} + \text{"B" Delay} + \text{"C" Delay} - \text{Overlapping Delay} - \text{Applicant Delay}$





PTA and Terminal Disclaimers

- PTA cannot be used to extend the term of a patent beyond the expiration date set in a filed (and approved) terminal disclaimer
- Standard USPTO terminal disclaimer form states that the disclaimed patent will not extend beyond the term of the prior patent
- Carefully consider whether a terminal disclaimer is required for all of the claims in an application
 - Claims that were previously subject to a restriction requirement in a parent application are protected from double patenting rejections over the elected claims under 35 U.S.C. § 121
 - Are all pending claims properly subject to the double patenting rejection? If not, consider whether to cancel the claims properly subject to the double patenting rejection.



PTA and Terminal Disclaimers - Examples

- Patent A filed on January 1, 2000
- Patent B is a continuation of Patent A
- Terminal Disclaimer filed in Patent B over Patent A

	Variation 1		Variation 2	
	Patent A	Patent B	Patent A	Patent B
PTA on Face of Patent	365	0	0	365
Effective PTA	365	0	0	0
Expiration Date	Jan. 1, 2021	Jan. 1, 2020	Jan. 1, 2020	Jan. 1, 2020



Reductions in PTA for Applicant Delays

- PTA awards are reduced by the failure of Applicants to engage in “reasonable efforts to conclude prosecution of the application”
- PTA is reduced for any failure to respond to an Office Action or other notice within 3 months (even if the period for responding without fees is shorter, e.g., Notices to File Missing Parts and Restriction Requirements)
- Other examples of Applicant delay are promulgated at 37 CFR § 1.704 and include:
 - Abandonment of an application
 - Submission of an incomplete reply
 - Submission of a supplemental reply (including, in some instances, an Information Disclosure Statement)
 - Submission of an amendment after a Notice of Allowance



Reinstatement of Reductions in PTA

- 35 U.S.C. § 154(b)(3)(C) – “The Director shall reinstate all or part of the cumulative period of time of an adjustment under paragraph (2)(C) if the applicant, prior to the issuance of the patent, makes a showing that, in spite of all due care, the applicant was unable to respond within the 3-month period, but in no case shall more than three additional months for each such response beyond the original 3-month period be reinstated.” (Emphasis added.)
- MPEP § 2734 indicates that “in spite of all due care” is more stringent than “unavoidable” standard



Reinstatement of Reductions in PTA

- Examples from MPEP § 2734:

Sufficient	Insufficient
3-month period was insufficient to obtain test data	Preoccupation with other matters
Natural disaster	Illness or death of practitioner associated with a law firm
Illness or death of sole practitioner	Time consumed by communications between applicant and representatives
	Vacation
	Use of first-class mail
	Improper docketing



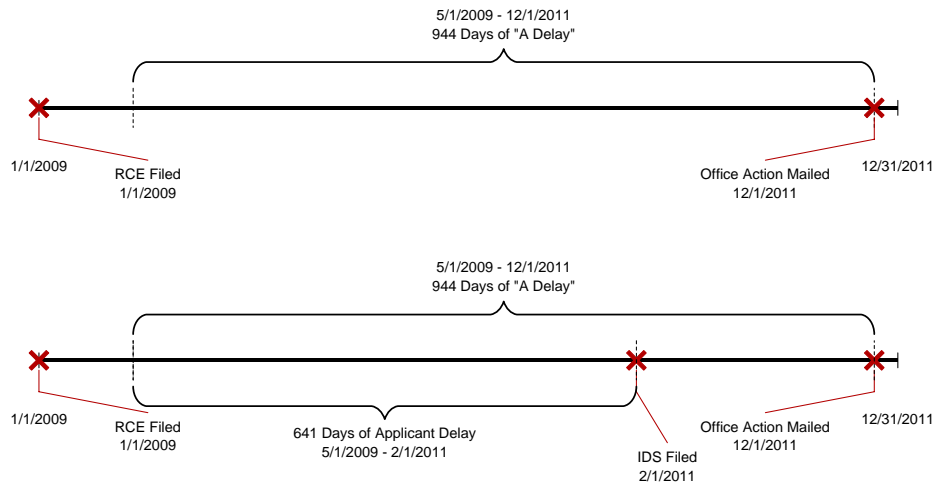
Deadlines Falling on Weekends or Holidays

- *ArQule v. Kappos* decision held that responses initially due on a weekend or holiday, but filed on the next business day, do not incur reductions of PTA due to Applicant Delay
 - ArQule filed suit seeking one additional day of PTA
 - Three-month deadline fell on Veterans Day
 - ArQule filed a response on the next day
 - USPTO reduced PTA award by one day of Applicant Delay
 - Court holds that 35 U.S.C. § 21(b)'s weekend and holiday exception to USPTO deadlines also applies to the PTA provisions of 35 U.S.C. § 154
- The USPTO acquiesced to the decision



Interactions Between Information Disclosure Statements and PTA

- An IDS filed after a response, but before next Office Action, is considered to be a supplemental response unless a certification is submitted under 37 CFR § 1.704(d) stating that:
 - Each reference included in the IDS is a communication or was first cited in a communication from the USPTO or a foreign patent office,
 - In a counterpart application, and
 - This communication was not received by any individual designated in 37 CFR § 1.56(c) more than 30 days (not one month) prior to the filing of the IDS





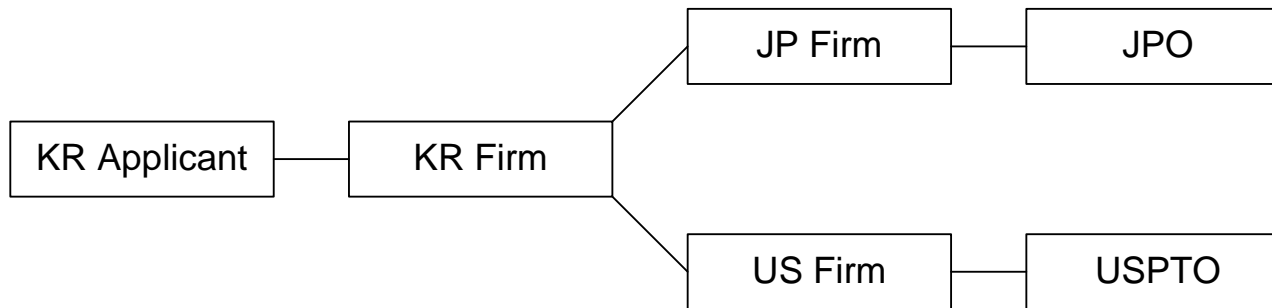
Interactions Between Information Disclosure Statements and PTA

- This deadline can be challenging to meet even for US applicants
- It is even more challenging (but still possible) for foreign applicants
- How to comply with § 1.704(d):
 - Understand when the 30-day clock begins
 - Clearly instruct US counsel to file IDS by the specified 30-day deadline



Interactions Between Information Disclosure Statements and PTA

- 30-day clock begins when reference or communication is received by an individual designated in § 1.56(c)
 - Likely includes foreign attorneys that direct the prosecution of patent family
 - Likely does not include foreign attorneys in other countries





Challenging PTA Calculations

- AIA Technical Corrections Act changed the procedure for challenging PTA for new patents
- Notice containing initial PTA calculation is no longer mailed with the Notice of Allowance
- The Issue Notification and the issued patent include the “final” PTA calculation
- No need to challenge PTA calculations when paying the issue fee except for requests for reinstatement of reductions under 35 U.S.C. § 154(b)(3)(C) and 37 CFR § 1.705(c)
- Detailed calculation is available at the USPTO PAIR portal
- Petitions challenging the USPTO's PTA must be filed within 2 months of issue (extendible by up to five months with payment of fees)
- Court actions challenging the USPTO's PTA must be filed in the Eastern District of Virginia within 180 days of USPTO decision



Open Issues

- When is an Office Action an Office Action?
- USPTO Rule Changes Regarding Pre-Appeal Briefs



Oncolytics Biotech. Inc. v. Kappos

- Patentee was unable to respond because of inadequacies in Office Action
- After an interview, the USPTO issued new Office Action stating that the previous Office Action is “vacated”
- USPTO’s PTA calculation treats the first Office Action as timely issued for purposes of four-month requirement
- USPTO asserts that the later *vacatur* of the first Office Action does not mean that the first Office Action was void *ab initio*
- Case stayed pending decision by USPTO on petition to invoke the Director’s supervisory authority
- Petition granted on May 24, 2012 awarding 122 days of PTA



USPTO Rule Change for PTA Effects of Pre-Appeal Brief Conference Pilot Program

- USPTO Pre-Appeal Brief Conference Pilot Program allows applicants to potentially avoid RCE or Notice of Appeal by filing short (<5 pages) arguments identifying clear factual or legal errors
- If successful, application is remanded to Examiner for new Office Action or allowance
- Request is filed with a Notice of Appeal
- Under old rules, Pre-Appeal Brief paused the accrual of "B" Delay
- However, a remand to the Examiner is not sufficient to produce "C" Delay
- USPTO recently changed its interpretation of the statute to allow accrual of "B" Delay until jurisdiction passes to the Patent Trial and Appeal Board (PTAB) when full appeal brief is filed



Tips for Maximizing PTA

- Inform US counsel if PTA is particularly important for application or client
- Avoid filing responses beyond three months
- File IDSs as soon as possible
- Inform US counsel if 30-day certification is desired and when the IDS must be filed
- Consider telephonic invention restrictions and elections of species
- Avoid terminal disclaimers
- Avoid requests for continued examination (RCEs)
- Effectively use divisional applications
- Engage counsel to review PTA calculations at allowance and issuance



Questions?

- Please feel free to contact me if you have any questions.

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Thank you!